

AMENDMENTS TO THE CLAIMS

1-9. (canceled)

10. (currently amended) A process for preparing an agglomerate ~~comprising of~~ potassium clavulanate, comprising;

a) ~~[[contacting]]~~ dissolving or suspending a potassium clavulanate crystal in a solvent or mixture of solvents in the presence of water to form a solution or suspension;

b) contacting said solution or suspension with an anti-solvent using a nozzle sprayer and under stirring using a stirring device ~~to cause precipitation of an agglomerate comprising potassium clavulanate,~~

~~wherein said agglomerate has a weight percentage of between 0 % and 10 % potassium clavulanate crystals in the needle form and is substantially free from non-agglomerate crystals in the needle form,~~ thereby precipitating an agglomerate of potassium clavulanate having a weight percentage of between 0 % and 10 % potassium clavulanate crystals in the needle form, and with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded.

11. (canceled)

12. (previously presented) A process according to claim 10, wherein the ratio of the weight of the solution containing the potassium clavulanate to the anti-solvent is about 0.05 to 10 wt.%.

13. (currently amended)) A process according to claim 10, wherein the solvent is water, ethanol, or a mixture thereof, ~~wherein water is present in said mixture.~~

14. (previously presented) A process according to claim 10, wherein the anti-solvent is a ketone, an ester, or an alcohol, or a mixture thereof, optionally containing water.

15. (canceled)

16. (previously presented) A process according to claim 10, wherein the stirring is performed by applying stirring devices in one or more vessels, in-line mixers or a combination thereof.

17. (previously presented) A process according to claim 16, wherein the stirring device is a high shear mixer.

18. (previously presented) A process according to claim 10, wherein said stirring is performed by combining and permuting different stirring devices, the speeds of said devices, the type and amount of the solvents used, and mixing one or more solvents and anti-solvents.

19. (previously presented) A process according to claim 10, wherein the agglomerate has an average particle size between about 1 μm and 1500 μm .

20. (previously presented) A process according to claim 10, wherein the process comprises dissolving the potassium clavulanate in a solvent, adjusting the pH to about neutral and mixing with the anti-solvent.

21-26. (canceled)

27. (previously presented) A process according to claim 19, wherein the agglomerate has an average particle size about 100 μm .

28. (previously presented) A process according to claim 19, wherein the agglomerate has an average particle size about 1000 μm .

29. (previously presented) A process according to claim 10, wherein the agglomerate has a bulk density between about 0.20 g/mL and 0.60 g/mL.

30. (canceled)

31. (currently amended) A process according to claim 10, wherein the agglomerate has a compressibility between about 10 % and 40 %, calculated as 100 times the ratio of the difference between tapped bulk density and loose bulk density to the tapped bulk density.

32-33. (canceled)

34. (previously presented) A process according to claim 10, wherein the agglomerate further comprises amoxicillin.

35. (previously presented) A process according to claim 10, wherein the agglomerate optionally contains one or more excipients.

36. (previously presented) A process according to claim 35, wherein the one or more excipients are selected from the group consisting of microcrystalline cellulose and silica.

37. (currently amended) An agglomerate of potassium clavulanate crystals, wherein said agglomerate has a compressibility between about 10 and 40 % calculated as 100 times the ratio of the difference between tapped bulk density and loose bulk density to the tapped bulk density, and said agglomerate has a weight percentage of between 0 % and 10 % potassium clavulanate crystals in the needle form and is precipitated from a solution obtained from contacting a potassium clavulanate crystal in a solvent or mixture of solvents with an anti-solvent under stirring, with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded.

38. (canceled)

39. (currently amended) The agglomerate of claim 37, further comprising [[amoxillin]] amoxicillin.

40. (previously presented) The agglomerate of claim 37, further comprising one or more excipients.

41. (previously presented) The agglomerate of claim 40, wherein said one or more excipients is selected from the group consisting of microcrystalline cellulose and silica.

42. (previously presented) The agglomerate of claim 37, wherein said agglomerate has an average particle size between about 1 μm and 1500 μm .

43. (previously presented) The agglomerate of claim 42, wherein said agglomerate has an average particle size of about 100 μm .

44. (previously presented) The agglomerate of claim 42, wherein said agglomerate has an average particle size of about 1000 μm .

45-46. (canceled)

47. (previously presented) A pharmaceutical formulation comprising the agglomerate of claim 37 and one or more pharmaceutically acceptable excipients.

48. (previously presented) The pharmaceutical formulation of claim 47, further comprising amoxicillin.

49. (previously presented) The pharmaceutical formulation of claim 47, wherein said one or more pharmaceutically acceptable inert excipients is selected from the group consisting of microcrystalline cellulose and silica.

50. (previously presented) A pharmaceutical dosage form comprising a pharmaceutical formulation of claim 47.

51. (previously presented) The agglomerate of claim 37, wherein said agglomerate has a loose bulk density of between about 0.2 g/mL and 0.6 g/mL.

52-53. (canceled)

54. (previously presented) The process of claim 10, wherein the solvent is aqueous acetone.

55. (currently amended) A process for preparing potassium clavulanate in the form of an agglomerate, comprising contacting a potassium clavulanate crystal in water or ethanol in the

presence of water, and contacting the resulting solution with an anti-solvent using a nozzle sprayer and under stirring using a stirring device to cause precipitation of an agglomerate comprising potassium clavulanate.

wherein said agglomerate has a weight percentage of between 0 % and 10 % potassium clavulanate crystals in the needle form, and with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded.

56. (previously presented) The process of claim 55, wherein the potassium clavulanate in water further comprises acetone.

57. (currently amended) The process of claim 55, wherein said anti-solvent ~~[[comprises]]~~ is acetone or ethyl acetate.

58-60. (canceled)

61. (new) The process of claim 10, wherein the average particle size and density of said agglomerate is controlled by the number of spray nozzles, spray nozzle diameter, solution flow through the nozzle or rotational speed of the mixer.

62. (new) The process of claim 10, wherein the particle size of said agglomerate is regulated by a combination and permutation of different stirring devices, the speeds of said devices, the type and amount of solvents, or the method of mixing said solvent and anti-solvent.

63. (new) The process of claim 10, wherein said solution or suspension is pumped through said nozzle to a vessel containing said antisolvent.

64. (new) The process of claim 63, wherein said vessel is equipped with a stirring device.

65. (new) The process of claim 64, wherein said stirring device is a high shear mixer.

66. (new) The process of claim 63, wherein an additional portion of antisolvent is simultaneously added to the vessel.

67. (new) An agglomerate prepared from the process of claim 10.